

DOCKET NO.: ADOL-0585

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Roland E. Dolle, et al.

Application No.: 10/713,746

Filing Date: November 14, 2003

For: AMIDE DERIVATIVES AND METHODS OF THEIR USE

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DATE OF DEPOSIT:

*April 19, 2004*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).



In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;

or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

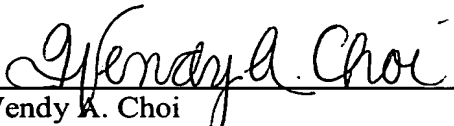
## EXCEPT THAT:

- ☒ In view of the voluminous nature of references 4, 6 and 22, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. \_\_\_\_\_, filed \_\_\_\_\_.

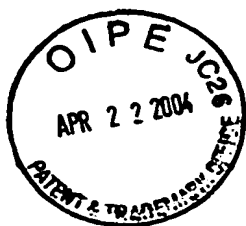
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- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: April 19, 2004

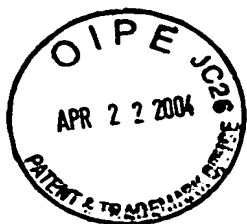
  
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. ADOL-0585	Application No. 10/713,746
		Applicant Roland E. Dolle, et al.	
		Filing Date November 14, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	1	Andreev, N., et al., "Opioids suppress spontaneous activity of polymodal nociceptors in rat paw skin induced by ultraviolet irradiation," <i>Neurosci.</i> , <b>1994</b> , 58(4), 793-798	
	2	Antonijevic, I. et al., "Perineurial defect and peripheral opioid analgesia in inflammation," <i>J. Neurosci.</i> , January <b>1995</b> , 15(1), 165-172	
	3	Barber, A., et al., "Opioid agonists and antagonists: an evaluation of their peripheral actions in inflammation," <i>Med. Res. Rev.</i> , <b>1992</b> , 12(5), 525-562	
*	4	Buschmann, H. (Eds.), et al., <i>Analgesics, Wiley-VCH, Verlag GmbH &amp; Co., KgaA, Weinheim, 2002</i>	
	5	Flynn, G.L., "Mechanism of percutaneous absorption from physicochemical evidence," Percutaneous Absorption, Maibach, H.I., et al. (Eds.), <i>Marcel Dekker Inc.</i> , <b>1985</b> , 17-42	
*	6	Greene, T.W., et al., <i>Protective Groups in Organic Synthesis</i> , 2 <sup>nd</sup> Ed., <i>Wiley &amp; Sons</i> , <b>1991</b>	
	7	Handwerker, et al., Pain and Inflammation, Proceeding of the VI <sup>th</sup> World Congress on Pain, Bond, et al. (Eds.), <i>Elsevier Science Publishers BV</i> , <b>1990</b> , 59-70	
	8	Hargreaves, K.M., et al., "The peripheral analgesic effects of opioids," <i>APS Journal</i> , <b>1993</b> , 2(1), 51-59	
	9	Hassan, A.H.S., et al., "Inflammation of the rat paw enhances axonal transport of opioid receptors in the sciatic nerve and increase their density in the inflamed tissue," <i>Neuroscience</i> , <b>1993</b> , 55(1), 185-193	
	10	Iyengar, S., et al., "Kappa opiate agonists modulate the hypothalamic-pituitary-adrenocortical axis in the rat," <i>J. Pharmacol. Exp. Ther.</i> , <b>1986</b> , 238(2), 429-436	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



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	11	Jain, K.K., "A guide to Drug Evaluation for chronic pain," <i>Emerging Drugs</i> , 2000, 5(2), 241-257		
	12	Leander, J.D., et al., "Diuresis and suppression of vasopressin by kappa opioids: comparison with Mu and Delta opioids and clonidine," <i>J. Pharm. Exp. Ther.</i> , 1985, 234, 463-469		
	13	Lurz, R.A., et al., "Opioid receptors and their pharmacological profiles," <i>J. of Recept. Res.</i> , 1992 12(3), 267-286		
	14	Mansour, A., et al., "Anatomical distribution of opioid receptors in mammals," an overview," <i>Opioid I</i> , 1993, 79-105		
	15	Manzanares, J., et al., "Kappa-opioid-receptor-mediated regulation of $\alpha$ -melanocyte-stimulating hormone secretion and tuberohypophyseal dopaminergic neuronal activity," <i>Neuroendocrinology</i> , 1990, 52, 200-205		
	16	Millan, M.J., "K-opioid receptors and analgesia," <i>Trends in Pharmacol. Sci.</i> , 1990, 11, 70-76		
	17	Morley, J.E., et al., "Involvement of dynorphin and the kappa opioid receptor in feeding," <i>Peptides</i> , 1983, 4, 797-800		
	18	Neugebauer, V., et al., "N-methyl-D-aspartate (NMDA) and non-NMDA receptor antagonists block the hyperexcitability of dorsal horn neurons during development of acute arthritis in rat's knee joint," <i>J. Neurosci.</i> , October 1993, 70(4), 1365-1377		
	19	Pershing, L.K., et al., "In vivo pharmacokinetics and pharmacodynamics of topical ketoconazole and miconazole in human stratum corneum," <i>Antimicrob. Agents Chemother.</i> , January 1994, 38(1), 90-95		
	20	Przewlocki, R., et al., "Gene expression and localization of opioid peptides in immune cells of inflamed tissue: functional role in antinociception," <i>Neuroscience</i> , 1992, 48(2), Pergamon Press Ltd., 491-500		
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	21	Ramabadran, K., et al., "A critical analysis of the experimental evaluation of nociceptive reactions in animals," <i>Pharm. Res.</i> , <b>1986</b> , 3(5), 263-270	
*	22	Remington's Pharmaceutical Sciences, <i>Mack Publishing Co.</i> , <b>1980</b>	
	23	Roy, S.D., et al., "Transdermal delivery of narcotic analgesics: pH, anatomical, and subject influences on cutaneous permeability of fentanyl and sufentanil," <i>Pharm. Res.</i> , <b>1990</b> , 7(8), 842-847	
	24	Sato, A., et al., "Changes in blood pressure and heart rate induced by movements of normal and inflamed knee joints," <i>Neurosci. Lett.</i> , <b>1984</b> , 52, 55-60	
	25	Schaible, H.-G., et al., "Effects of an experimental arthritis on the sensory properties of fine articular afferent units," <i>J. of Neurophysiol.</i> , <b>1985</b> , 54(5), 1109-1122	
	26	Schaible, H.-G. et al., "Afferent and spinal mechanisms of joint pain," <i>Pain</i> , <b>1993</b> , 55, 5-54	
	27	Simon, E.J., "Opioid receptors and endogenous opioid peptides," <i>Med. Res. Rev.</i> , <b>1991</b> , 11(4), 357-374	
	28	Stein, C., et al., "Peripheral opioid receptors mediating antinociception in inflammation. Evidence for involvement of MU, Delta, and Kappa receptors," <i>J. Pharmacol. Exp. Ther.</i> , <b>1989</b> , 248(3), 1269-1275	
	29	Stein, C., et al., "Peripheral effect of fentanyl upon nociception in inflamed tissue of the rat," <i>Neurosci. Lett.</i> , <b>1988</b> , 84, 225-228	
	30	Stein, C., et al., "Unilateral inflammation of the hindpaw in rats as a model of prolonged noxious stimulation: alterations in behavior and nociceptive thresholds," <i>Pharmacol. Biochem. &amp; Behav.</i> , <b>1988</b> , 31, 445-451	
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	31	Taber, R.I., et al., "Agonist and antagonist interactions of opioids on acetic acid-induced abdominal stretching in mice," <i>J. or Pharmacol. Exp. Ther.</i> , <b>1969</b> , 169(1), 29-38		
	32	Tjølsen, A., et al., "The formalin test: an evaluation of the method," <i>Pain</i> , <b>1992</b> , 51, 5-17		
	33	Wheeler-Aceto, H., et al., "Standardization of the rat paw formalin test for the evaluation of analgesics," <i>Psychopharmacology</i> , <b>1991</b> , 104, 35-44		
	34	Williamson, J.W., et al., "Reflex increase in blood pressure induced by leg compression in man," <i>J. Physiol.</i> , <b>1994</b> , 475.2, 351-357		
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<b>U. S. PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	
	36	4,065,573	12/27/77	Lednicer	424	278	
	37	4,098,904	07/04/78	Szmuszkowicz	424	324	
	38	4,145,435	03/20/79	Szmuszkowicz	424	274	
	39	4,212,878	07/15/80	Lednicer, et al.	424	274	
	40	4,359,476	11/16/82	Kaplan, et al.	424	274	
	41	4,438,130	03/20/84	Kaplan	424	274	
	42	4,663,343	05/05/87	Horwell, et al.	514	429	
	43	4,906,655	03/06/90	Horwell, et al.	514	422	
	44	5,109,135	04/28/92	D'Ambra, et al.	544	73	
	45	5,242,944	09/07/93	Park, et al.	514	466	
	46	5,345,943	09/13/94	Hargreaves, et al.	128	742	
	47	5,369,131	11/29/94	Poli, et al.	514	772.4	
	48	5,434,292	07/18/95	Saita, et al.	560	51	
	49	5,532,266	07/02/96	Gottschlich, et al.	514	428	
	50	5,688,955	11/18/97	Kruse, et al.	546	276.4	
	51	5,804,595	09/08/98	Portoghese, et al.	514	428	
	52	6,117,438	09/12/00	Topolkaraev, et al.	424	404	
<b>EXAMINE</b>				<b>DATE CONSIDERED</b>			